K123732
pg. 1 of 4

WORLD OF MEDICINE
Hysteroscopy Pump HM6
Special 510(k) Premarket Notification

APR 0 4 2013

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Submitter: W.O.M. WORLD OF MEDICINE AG
Salzufer 8
10587 Berlin
Germany

Phone: +49 30 399 81 594
Fax: +49 30 399 81 593

Contact Person: Susanne Raab
Regulatory Consultant
1480 Cambridge Street
Cambridge, MA 02139

Phone: (617) 547-0628
Fax: (617) 520-2401
e-mail: sbraab@comcast.net

Date Prepared: December 4, 2012

Trade Name: Hysteroscopy Pump HM6

Common Name: Hysteroscopic Insufflator, Fluid Monitoring System and Tube Sets

Classification Name: Hystersoscopic Insufflator and Accessories under 21 C.F.R. 884.1700

Regulatory Class: II

Product Code: HIG

Predicate Devices:

- Aquilex Fluid Control System H112 (K112642)
- Hysteroscopy Pump HM4 (K022449)

Device Description:

The Hysteroscopy Pump HM6 is a microprocessor controlled device that consists of the following two main components: (1) an irrigation pump unit and (2) and fluid monitoring unit that are to be placed on a cart. The irrigation pump unit is a single roller pump that functions according to the peristaltic system and includes a man-machine interface (MMI) and a touch-screen display. The Hysteroscopy Pump HM6 is to be used with specially designed single use irrigation and outflow tube sets that are supplied sterile. The fluid monitoring unit of the Hysteroscopy Pump HM6 is a microprocessor controlled device, which monitors the amount of delivered irrigation solution and compares it with the volume of the secretions returned to the container. The monitoring enables the surgeon to observe the quantity of fluids left in the patient. The irrigation pump unit of the proposed device indicates any fluid deficit that exceeds the fluid deficit level pre-set by the surgeon. The Hysteroscopy Pump HM6 determines both the inflow and outflow volume by means of two separate scales.

Intended Use:

The Hysteroscopy Pump HM6 is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.

Summary of Similarities and Differences in Technological Characteristics:

The proposed device Hysteroscopy Pump HM6 is a modified version of the Aquilex Fluid Control System H112, K112642, (the "Aquilex System"). The Hysteroscopy Pump HM6 and the Aquilex System use the same basic operating principles and incorporate the same basic design including materials. Specifically, the Hysteroscopy Pump HM6 and the Aquilex System incorporate the following main components: (i) an irrigation pump unit, (ii) a fluid monitoring unit, and (iii) an inflow and an outflow tube set.

The irrigation pump units of both the proposed device Hysteroscopy Pump HM6 and Aquilex System are all electro-mechanical and microprocessor controlled devices that function according to the peristaltic principle. Both the Hysteroscopy Pump HM6 and the Aquilex System utilize a pressure sensor to monitor the intrauterine pressure. To achieve the desired pressure within the cavity, the pressure sensor of both the Hysteroscopy Pump HM6 and the Aquilex System are connected to a processor that controls the speed of the roller wheel and thus the volume of fluid that is delivered into the cavity. The maximum selectable pressure of the Hysteroscopy Pump HM6 is identical to that of the Aquilex System (150 mmHg). Furthermore, both the Hysteroscopy Pump HM6 and the predicate devices are

designed with the same or similar setting keys, display elements and safety features (e.g. active pressure reduction, overpressure warnings and fluid deficit warnings). The fluid monitoring unit of both the proposed device Hysteroscopy Pump HM6 and Aquilex System are micro-processor controlled devices, which monitor the amount of delivered irrigation solution and compare it with the volume of the secretions returned to the container. The fluid monitoring unit consists of the following main components: (1) scale, (2) a support plate, (3), a bag holder, (4) a container holder, and (5) a roller base. Finally, the inflow tube set and outflow tube set of the proposed device Hysteroscopy Pump HM6 is identical in design, material, packaging and sterilization to the inflow and outflow tube set of the Aquilex System except for a minor change to the length of the tubing that is attached to the Y-connector of the inflow tube set and the equipment of the outflow tube set with an additional clamp. Also, the outflow tube set of the Hysteroscopy Pump HM6 is not designed with suction connectors.

The modification to the predicate device Aquilex System consists of a change in software and design. The main differences are related to the inclusion of a man-machine interface (MMI) including a 7" touch-screen and to the incorporation of a separate scale for determination of the inflow volume. Also, unlike the Aquilex System, the Hysteroscopy Pump HM6 is not equipped with vacuum pumps and therefore, not capable of applying suction. Other minor differences include the location of the roller wheel at the front of the device, a reduction of the maximum flow rate, the ability to choose a flow rate, the ability to use the irrigation pump unit without fluid monitoring unit and the optional performance of the instrument detection feature.

Substantial Equivalence:

The Hysteroscopy Pump HM6 is substantially equivalent to the Aquilex System (K112642) and to the Hysteroscopy Pump HM4 (K022449). The proposed device has the same intended use as the predicate devices. In addition, both the proposed device and the predicate devices incorporate the same fundamental scientific technology. Specifically, both the predicate device and the predicate devices use the same basic operating principles and incorporate the same basic design.

The differences between the Hysteroscopy Pump HM6 and the predicate device Aquilex System are minor and do not raise new questions of safety and effectiveness.

Specifically, the implementation of an interactive man-machine interface (MMI) including a 7" touch screen display into the proposed device as well as the modification that are related the above changes (e.g. incorporation of a faster processor, larger casing of the irrigation pump unit, optional display of the set flow rate and graphical display fluid deficit in % of the set pressure limit) improve the ease of use of the proposed device and do not raise new questions of safety and effectiveness. In addition, the incorporations of a separate scale to determine the

inflow volume for calculation of the fluid deficit including any related modifications do not raise new questions of safety and effectiveness. Not only improves the use of a separate scale the accuracy of the fluid deficit measurement from volume measurement ± 10 % to ± 6 % compared to the predicate device Aquilex System but also allows for the implementation of the empty fluid bag detection feature as a new safety feature that informs the user if the fluid in the fluid bag is <= 500 ml. With regards to the location of the roller wheel at the front of the device, the reduction of the maximum flow rate, the ability select a flow rate, the ability to use of the irrigation pump unit without fluid monitoring unit and the optional performance of the instrument detection feature, the proposed device is substantially equivalent to the predicate device Hysteroscopy Pump HM6. In addition, all other minor differences do not raise new questions of safety and effectiveness. Finally, testing demonstrates that the differences between the Hysteroscopy Pump HM6 and the predicate devices do not raise new questions of safety and effectiveness. Based on the same intended use and indication for use and the similiarities in technolgy, design and materials, the Aquilex System is substantially equivalent to its predicate devices.

Performance Testing:

The design modifications, which affect both the mechanical, hardware and software design, are considered appropriate for reliance on the results from the internal design control process, including risk analysis.

Validation and verification testing of the system specification were performed as bench tests.

Software validation was performed in accordance with the FDA Guidance document "Gerneral Principles of Software Validation". The Software of the Hysteroscopy Pump HM6 is considered "Major Level of Concern".

Electrical Safety and EMC testing was performed in accordance with IEC 60601-1 by an accredited test institute.

The labeling has been updated to reflect the design modifications.

Conclusion:

Based on the same intended use the similiarities in technolgy, design and materials, the Hysteroscopy Pump HM6 is substantially equivalent to its predicate devices. The differnences between the proposed device and the predicate devices are minor and do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2013

W.O.M. WORLD OF MEDICINE AG
% Ms. Susanne Raab
Regulatory Consultant
1480 Cambridge Street
CAMBRIDGE MA 02139

Re: K123732
Trade/Device Name: Hysteroscopy Pump HM6
Regulation Number: 21 CFR§ 884.1700
Regulation Name: Hysteroscopic insufflator
Regulatory Class: II
Product Code: HIG
Dated: March 18, 2013
Received: March 21, 2013

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

WORLD OF MEDICINE
Hysteroscopy Pump HM6
Special 510(k) Premarket Notification

INDICATIONS FOR USE STATMENT

510(k) Number (if known): K123732

Device Name: Hystersocopy Pump HM6

Indications for Use:

The Hysteroscopy Pump HM6 is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.04.04 18:12:43 -04'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123732